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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,425	06/06/2007	Todd C. Zankel	30610/39385A	5100

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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
03/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,425	ZANKEL ET AL.	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Preliminary amendments respectively filed 04 August 2006, 05 March 2009 and on 05 June 2009 are acknowledged and entered.

Informal Matters

2. The instant application (i.e., 10/588,425) has been assigned to Art Unit 1657 at the United States Patent and Trademark Office (i.e., USPTO). To aid in correlating any papers for the instant application, all further correspondence regarding the instant application (i.e., 10/588,425) should be directed to Art Unit 1657.

3. The assigned Examiner to the above-cited application (i.e., 10/588,425) at the USPTO is Kailash C. Srivastava. To aid in correlating any papers for the instant application, all further correspondence regarding the instant application (i.e., 10/588,425) should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

4. The following Office Action addresses all the amendments cited *supra*.

Claims Status

5. Claims 1-30 are currently cancelled.

6. Claims 31-35 have currently been added.

7. Claims 31-35 are currently pending.

Election /Restriction

8. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1and 37 C.F.R. §1.475. Restriction to one of the following inventions is required under 35 U.S.C. §121 and §372.

In accordance with rules cited *supra*, applicant(s) is/are required, in reply to this Office Action, to select a single invention to which the claims must be restricted.

- Group I, consisting of claims 31-34 drawn to a composition comprising human α-glucosidase (i.e., rhGAA), wherein uptake of said rhGAA in to fibroblast cells have an uptake

of ≤10nm and said composition also comprises a pharmaceutically acceptable carrier, diluent, or excipient ;

- Group II, consisting of claim 35, drawn to a method to treat Pompe disease resulting from a deficiency of a lysosomal enzyme, said method comprising administering said rhGAA to a subject in need thereof.

Inventions are Independent or Distinct

9. The inventions listed in Groups I-II above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The patent rules under 37 C.F.R. §1.475 for Unity of Invention (Paragraphs (a), (b) and (c)) are cited below:

§1.475 Unity of Invention before the International Searching Authority, the International Preliminary Examining Authority and during the National Stage

(a) An International and National Stage Application shall relate to one invention only, or to a group of inventions so linked as to form a general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as whole, makes over the prior art.

(b) An International or a National stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

Inventions described in Groups I-II *supra* fall within category (2), a product and a method of use of said product.

10. PCT Rule 13.2 does not provide for multiple compositions, or multiple methods of making a composition, or multiple methods of use of a composition within a single application. Thus, the first appearing composition is combined with a corresponding first method of making said composition (if applicable) and/ or use of said composition. However, the additional composition and method claims each constitute a separate inventive Group.

In addition to the requirement that a Group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, e.g., as a composition and a method of use of said composition, must have a special technical feature that unites them. See Patent rules under 37 C.F.R. §1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

The special technical feature of the group I composition is well known in the relevant art (see, e.g., Applicants' IDS filed 03 October 2008, NPL item 2-Amalfitano et al., 2001. Recombinant human acid α-glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase I/II clinical trial. Genetics In Medicine, Volume 3, Number 2, Pages: 132-138; Page 133, Column 2, Lines 27-33). Since said enzyme was obtained in solution, said composition intrinsically comprised a pharmaceutical excipient).

The special technical feature of Group II Method, that of administering a pharmaceutically acceptable composition comprising rhGAA to treat Pompe disease resulting from a deficiency of a lysosomal enzyme to a subject in need thereof is also well known in the relevant art (see, e.g., Applicants' IDS filed 03 October 2008, NPL item 2-Amalfitano et al., 2001. Recombinant human acid α-glucosidase enzyme therapy for infantile glycogen storage disease type II: Results of a phase I/II clinical trial. Genetics In Medicine, Volume 3, Number 2, Pages: 132-138; Abstract, Lines 11-17; Page 132, Column 1, Lines 29-34; Table 2).

Thus, the claimed composition and method lack unity of invention because the alleged special technical feature is not a contribution over the prior art.

11. In accordance with 37 C.F.R. §1.499, applicant (S) is/are required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant(s) is/are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 C.F.R. §1.143).

12. Applicant (s) is/are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. §1.116; amendments submitted after allowance are governed by 37 C.F.R. §1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. §1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §101, §102, §103, and §112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise

include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. §804.01.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

/Kailash C Srivastava/
Examiner, Art Unit 1657

Kailash C. Srivastava
Examiner
Art Unit 1657
(571) 272-0923

25 March 2010

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657